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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,381	BERNASCONI ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *3,5,11,13 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,2,4,6-10,12,14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *n/a* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 10/30/03, have been entered in full.

Applicant's election (10/23/03) of the species of methods of treating Parkinson's disease is acknowledged. Applicant asserts that claims 1, 2, 4, 6-10, 12, 14, and 16 read on the elected invention.

Claims 3, 5, 11, 13, 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. As no arguments were presented as to why the restriction requirement might be improper, the election is treated as being made **without** traverse; thus the restriction requirement is maintained and made FINAL. Applicant is reminded that the claims will be examined in this Office action only to the extent that they read on the elected invention, i.e. methods of treating Parkinson's disease.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims1, 2, 4, 6, 7, 9, 10, 12, 14 and 16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 6, 7, 9, 10, 12, 14 and 16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim s provides for the use of either increasing Neurotrophin levels in the CNS, e.g. claim 1, or for treating a disorder, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9 and 10 require a therapeutically effective amount of a $GABA_B$ receptor antagonist, yet the claims do not stipulate what the amount is to be effective for, i.e. there is no requirement in either claim that the amount be effective for treating the recited disorder; thus the artisan could not know whether or not he or she was practicing the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 6-10, 12, 14 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the art recognized treatment of Alzheimer's disease, does not reasonably provide enablement for methods of treating Parkinson's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification discloses that $GABA_B$ receptor antagonists have been found to increase the amounts of nerve growth factor (NGF) and brain-derived nerve factor (BDNF). Based on this, the specification makes the speculation that $GABA_B$ receptor antagonists should be useful in the treatment of a variety of neurodegenerative disorders. However, no data of any kind is provided to support this speculation. One of skill in the art appreciates that the variety of disorders listed in the first paragraph of page 5 result from distinct and divergent etiologies, involve disparate cell types and have largely been found to be recalcitrant to treatments, particularly those involving neurodegeneration. Further, $GABA_B$ receptor antagonists have now been well studied in the art, and it would not be predictable that $GABA_B$ receptor antagonists would have any benefit in the treatment of Parkinson's disease. This has been born-out by Zeevalk, GD et al., Experimental Neurology 176(193-202)2002 who found that the $GABA_B$ receptor antagonist Saclofen was without effect on the malonate-induced toxicity of straital dopamine neurons in a mouse model of Parkinson's disease (see the last paragraph of page 195). Moreover, Zeevalk, GD et al. review the state of the art and conclude that their findings were not surprising in view of the prior art, such art being available at the time the instant application was filed, see the middle paragraph of page 198. Never-the-less, Yu et al. Brain Research

750(53-58)1997, found that a $GABA_B$ receptor antagonist protected hippocampal cells from colchicine-induced damage in an animal model of Alzheimer's disease, see the Abstract

Therefore due to the large quantity of experimentation necessary to try to find away to treat disorders other than Alzheimer's disease with a $GABA_B$ receptor antagonist, as taught by Yu et al., if such a way can be found, the lack of direction/guidance presented in the specification regarding which disorders, if any, are amenable to such treatment, the absence of working examples directed to same, the complex nature of the many disparate disease states contemplated by the claims, the contradictory state of the state of the prior art as reviewed by Zeevalk, GD et al and also validated by the same authors, and the breadth of the claims which encompass perhaps the whole spectrum of disparate neurodegenerative disorders, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 7, 8, 9, 10, 12, 14, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. Brain Research 750(53-58)1997.

The specification puts forth that Alzheimer's disease is a disorder that is responsive to an increase in the neurotrophin factors NGF and BDNF and that $GABA_B$ receptor antagonists increase the amounts of these factors and are useful for treating Alzheimer's disease (pages 4-5).

Yu et al. successfully treat mice suffering from a mouse-model of Alzheimer's disease with a $GABA_B$ receptor antagonist, see the Abstract. Thus, it would be an inherent feature of their method that NGF and BDNF would be increased, absent evidence to the contrary. Further more, Yu et al use a pharmaceutical composition comprising the $GABA_B$ receptor antagonist, see col 1 of page 54.

Conclusion

No claims are allowable

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564 until January 22, 2003 and at (571) 272-0871 thereafter.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

January 18, 2004